UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,641	01/22/2004	Nikhilesh N. Singh	872,521-041	7706

34263 7590 09/30/2009

O"Melveny & Myers LLP
IP&T Calendar Department LA-13-A7
400 South Hope Street
Los Angeles, CA 90071-2899

EXAMINER
STONE, CHRISTOPHER R

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,641	SINGH ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *5,7-12,21,23,42,44,56 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 13-20, 22, 24-41, 43, 45-55, 57, 59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the compositions of Group I (claims 1-60), ondansetron, sodium carbonate/sodium bicarbonate buffer system, a dissolving tablet, and the composition without gum base in the reply filed on July 21, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5, 7-12, 21, 23, 42, 44, 56 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 13-20, 22, 24-41, 43, 45-55, 57, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinney et al (WO 01/89476 A1, cited on IDS, filed December 6, 2004) in view of Luo et al (US 2001/0051166 A1).

Claims 1-4, 6, 13-20, 22, 24-41, 43, 45-55, 57, 59 and 60 are drawn to a composition for delivering a 5-HT3 antagonist across the oral mucosa comprising: the 5-HT3 antagonist, ondansetron, wherein ondansetron is at least partly in an ionized form, the ionized form capable of being converted into an un-ionized form; and a buffer system, wherein the buffer system comprises sodium carbonate and sodium bicarbonate and is capable of changing the pH of saliva from an arbitrary initial pH to a predetermined final pH, independent of the arbitrary initial pH, and of sustaining the predetermined final pH for a period of time, in the form of a dissolving tablet.

Pinney et al (WO 01/89476 A1, cited on IDS, filed December 6, 2004) teaches a composition for delivering a 5-HT3 antagonist across the oral mucosa comprising (abstract): the 5-HT3 antagonist, granisetron (p. 13, line 22), wherein granisetron is at least partly in an ionized form, the ionized form capable of being converted into an un-ionized form; and a buffer system, wherein the buffer system comprises, for example, sodium carbonate and sodium bicarbonate and is capable of changing the pH of saliva from an arbitrary initial pH to a predetermined final pH, including for example pH 7-10, independent of the arbitrary initial pH, and of sustaining the predetermined final pH for a

period of time, e.g. 3-30 minutes (which encompasses 5-10 minutes) and protecting agents, i.e. preservatives (p. 12, lines 27 and 28, p. 6, last paragraph to p. 7, first paragraph and p. 9, line 4), in the form of a dissolving tablet (p. 5, lines 18-22). Pinney et al does not explicitly teach the 5-HT3 antagonist ondansetron in place of the 5-HT3 antagonist, granisetron, the amount of ondansetron converted into the unionized form in the particular times specified by claims 13-18, the ratio of buffering agents specified in claims 24-28 and 45-49, the composition further comprising a penetration enhancer or the pharmacokinetic and membrane permeability parameters specified by claims 35-37.

Luo et al (US 2001/0051166 A1) teaches that the 5-HT3 antagonist ondansetron is useful when administered in transmucosal dosage forms and that penetration enhancers are useful in transmucosal dosage forms to increase the rate at which a drug penetrates mucosal tissue (paragraphs 0005, 0041, 0063 and 000070).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to use the 5-HT3 antagonist ondansetron in place of the 5-HT3 antagonist, granisetron, in the composition of Pinney et al, since both compounds were 5-HT3 antagonists known to be useful when administered transmucosally, and to add a penetration enhancer to the composition of Pinney et al, since penetration enhancers were known to increase transmucosal drug absorption. Additionally with regard to the amount of ondansetron converted into the unionized form in the particular times specified by claims 13-18, the ratio of buffering agents specified in claims 24-28 and 45-49 and the pharmacokinetic and membrane permeability parameters specified by claims 35-37; the amount of unionized present is a

function of pH and as noted above, Pinney et al teaches a pH range (i.e. 7-10) which is encompassed by the instantly claimed pH values. Furthermore, Pinney et al explicitly teaches that the pH and buffer components can be varied by routine experimentation by one of ordinary skill in the art to adjust the release of the active agents over a period of time and that the active agent may be released immediately or sustained (p. 10, first paragraph).

Therefore it would also have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to optimize the buffer ratio and ondansetron converted into the unionized form in the particular times to accomplish an appropriate release profile (i.e. appropriate pharmacokinetic and membrane permeability parameters) for a given circumstance, thus resulting in the practice of the instantly claimed invention with only routine experimentation while having a reasonable expectation of success. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645